

PATENT  
Application No. 09/868,379  
Filing Date: 08/15/2001  
Examiner: Frederick F. Krass  
Art Unit: 1614  
Attorney Docket No. H03763/219-06

EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the United States Patent Application of :

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Application Serial No. 09/868,379  
Filing Date: 08/15/2001  
Claiming priority of International Application  
PCT/EP99/09683, filed 12/09/1999  
and German Application  
DE 198 53 662 0, filed 12/18/1998

Examiner: Frederick F. Krass  
Art Unit: 1614

Assignee: Henkel KGaA

Title: FINE SUSPENSIONS OF POORLY SOLUBLE CALCIUM SALTS  
AND THEIR USE IN DENTAL CARE PRODUCTS

THIRD DECLARATION OF CHRISTIAN KROPF

I, Christian Kropf declare as follows:

1. I am an inventor of United States Patent Application No. 09/868,379.
2. I am the head of a department in Corporate Research Chemistry at Henkel KGaA, Henkelstrasse 67, 40589 Düsseldorf, Germany. I obtained both a diploma degree in Chemistry in 1992 and a Ph.D. degree in Engineering Sciences (new materials) in 1998 from Saarland University in Saarbruecken, Germany.

3. I am familiar with United States Patent Application No. 09/868,379 of Christian Kropf et al. (hereinafter the "Kropf application"), United States Patent No. 6,919,070 to Rudin et al. and United States Patent No. 4,098,878 to Baines et al.

4. Claim 8 of the Kropf application is directed to a suspension. The remaining claims 9, 13-16 and 20-25 are directed to a toothpaste comprising the suspension, a method of remineralizing teeth comprising the suspension, or other suspensions within the scope of claim 8. Claim 8 reads as follows:

Claim 8. A suspension of one or more phosphate calcium salts, fluoride calcium salts, or fluorophosphate calcium salts in a liquid medium in which the salts are less than 1 g/l soluble, wherein the calcium salts comprise primary particles having diameters of from 5 to 50 nanometers and lengths of from 10 to 150 nanometers, stabilized against agglomeration by a content of at least 0.01% by weight, based on the weight of the suspension, of a water-soluble polymeric protective colloid selected from the group consisting of gelatin, casein, starch, plant gums, cellulose ethers, methylcellulose, hydroxyethylcellulose, carboxymethylcellulose, hydroxyethylstarch and hydroxypropyl guar, adsorbed onto said particles.

5. The Rudin et al. patent discloses a composition characterized in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d), and thickness (h). The values for these dimensions are: (l) from 0.2  $\mu\text{m}$  to 0.01  $\mu\text{m}$ , (d) 0.1  $\mu\text{m}$  to about 0.001  $\mu\text{m}$  and (h) from 0.1  $\mu\text{m}$  to 0.0001  $\mu\text{m}$  (column 2, lines 22-27).

6. Rudin et al. further discloses that the hydroxyapatite being introduced into the composition possesses osteo-reparative properties and contains preferably about 100%  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$  and that the specific surface of hydroxyapatite used in the composite advantageously is 100 to 150  $\text{m}^2/\text{g}$  (column 2, lines 41-45). This disclosure indicates that the hydroxyapatite disclosed in Rudin et al. is pure hydroxyapatite.

7. Rudin et al. further discloses an oral product that will comprise a liquid phase containing humectants and binding thickeners which act to maintain the particulate solid abrasive and hydroxyapatite crystals in the form of stable suspension in liquid phase (column 3, lines 11-15). On the basis of the disclosure in Rudin et al. identified in Paragraph 6 of my Declaration, the hydroxyapatite crystals in the suspension are pure hydroxyapatite.

8. My conclusion that the hydroxyapatite particles disclosed in Rudin et al. are pure is further based on the disclosure at column 2, lines 46-51 of Rudin et al. that U.S. Patent No. 6,254,855 B1 describes a method for producing a suspension of hydroxyapatite as described in the Rudin et al. application. U.S. Patent No. 6,254,855 B1 discloses in Example 1 that according to the method described in that patent, a pure stoichiometric hydroxylapatite in a suspension form is produced free of admixtures (column 3, lines 43-67).

9. The calcium particles claimed in Claim 8 of the Kropf application are not pure hydroxyapatite. They are particles of calcium salt with a colloid selected from a group of water-soluble polymeric protective colloids adsorbed onto said particles. Accordingly, the particles claimed in the Kropf application are different in composition than the pure hydroxyapatite particles disclosed in Rudin et al.

10. A comparison of the suspension claimed in Claim 8 with the suspension disclosed in Rudin et al. reveals that the claimed suspension is distinct from the suspension taught or suggested by Rudin et al. Rudin et al. discloses crystals of pure hydroxyapatite of a defined particle size that are maintained in a suspension. Applicants' claimed suspension is of particles of calcium salts, wherein a defined water-soluble polymeric protective colloid is adsorbed onto said particles. Accordingly, Rudin et al. does not disclose or suggest Applicants' claimed suspension comprising particles of one or more calcium salts with a colloid adsorbed onto said particles, which is set forth in all of Applicants' pending claims 8-9, 13-16 and 20-25.

11. The Baines et al. patent is directed to dentifrices containing as a dental abrasive, milled alpha-alumina trihydrate, which has been surface-treated with a higher fatty acid (Abstract).

12. As disclosed in Baines et al., milled alpha-alumina trihydrate tends (particularly when it is of a less alkaline type) to react with sodium fluoride. An analysis of freshly prepared toothpaste gives values of soluble fluoride much lower than when the abrasive is inert (column 1, lines 8-13).

13. Baines et al. discloses that pre-treating the trihydrate with 1% stearic acid greatly inhibits the reaction of the trihydrate and sodium fluoride (column 1, lines 24-29. This disclosure is further set forth in EXAMPLES 1 and 2 at column 1, line 35 to column 3, line 18).

14. Baines et al. further discloses that the protection of the surfaces of the particles of abrasive in the dentifrice to reduce the chemical activity of the surfaces thereof, e.g. to prevent or hinder passage of components of the abrasive into the aqueous medium of the dentifrice, this protection being effected by means of a surface treatment with a water-insoluble material that adheres to active sites of said particles (column 6, lines 39-46). The particles may be maintained in substantially unagglomerated form (column 6, lines 60-61).

15. The treating materials may be any of the following:
- (a) a waxy or high viscosity greasy material may be applied in a solvent (column 6, lines 50–51);
  - (b) polar materials including, for example higher ( $C_6$ – $C_{22}$ ) fatty alcohols and higher fatty acids, such as lauric and stearic acids and lauryl and stearyl and alcohol (column 7, lines 11–12 and 17–20);
  - (c) non-polar materials including waxes, vegetable oils such as palm oil and hydrogenated palm oil, and hydrocarbon oils and greases, e.g. mineral oils such as liquid paraffin, e.g., light or heavy petrolatum, petroleum jelly and petroleum wax (column 7, lines 11–12 and 28–30); and
  - (d) a surface-active agent of the cationic or amphoteric categories (column 7, lines 32–33).

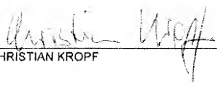
16. Baines et al. does not exemplify, disclose or suggest to one of ordinary skill in the art the use of treating materials selected from a water-soluble polymeric protective colloid selected from the group consisting of gelatin, casein, starch, plant gums, cellulose ethers, methylcellulose, hydroxyethylcellulose, carboxymethylcellulose, hydroxyethylstarch and hydroxypropyl guar.

17. Baines et al. does not exemplify, disclose or suggest to one of ordinary skill in the art a suspension of one or more phosphate calcium salts, fluoride calcium salts, or fluorophosphate calcium salts in a liquid medium.

18. For the reasons set forth above, the Rudin et al. and the Baines et al. suspensions of particles are distinct from Applicants' claimed suspension of particles of calcium salt wherein a water-soluble polymeric protective colloid, as defined in Applicants' Claim 8, is adsorbed onto said particles. Indeed, Baines et al. contains no disclosure or suggestion about attempting to adsorb a colloid onto the particles. Accordingly, Baines et al., like Rudin et al., does not disclose or suggest Applicants' claimed suspension comprising particles of calcium salt with the colloid as defined in Claim 8 adsorbed onto said particles, which is set forth in all of Applicants' pending claims, 8-9, 13-17 and 20-25.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 19 of the United States Code, and that such willful false statements may jeopardize the validity of the Kropf application or any patent issued thereon.

Dated: January 31, 2008

  
CHRISTIAN KROPF